

CLAIMS

What is claimed as the invention is:

*sub a/*

1. A method of inducing sustained immunological tolerance in an individual to a target antigen, comprising administering to a mucosal surface of the individual a composition comprising an effective combination of an inducing antigen and a mucosal binding component in an unconjugated form.
2. The method of claim 1, wherein the mucosal binding component has GM1 binding activity.
3. The method of claim 1, wherein the mucosal binding component is a cholera toxin B peptide.
4. The method of claim 1, wherein the inducing antigen and the mucosal binding component are unassociated in the composition.
5. The method of claim 1, wherein the inducing agent is the target antigen.

*sub b/*

6. The method of claim 1, wherein the inducing agent is a bystander for the target antigen.

*sub a<sup>2</sup>/*

7. The method of claim 1, wherein the mucosal surface is the gastrointestinal mucosa and the composition is administered orally.
8. The method of claim 1, wherein the mucosal surface is the nasal mucosa and the composition is administered nasally.

9. The method of claim 1, wherein the mucosal surface is the airway mucosa and the composition is administered by aerosol.
10. The method of claim 1, comprising administering the composition to the mucosal surface on at least three successive occasions.
11. The method of claim 1, wherein the sustained immune tolerance persists for at least 5 weeks.
12. A method of inducing sustained immunological tolerance in an individual to an allergen or a mucosal antigen, comprising administering to a mucosal surface of the individual a composition comprising an effective amount of a mucosal binding component.  
*sub a<sup>3</sup>*
13. The method according to claim 12, wherein immunological tolerance is induced against an allergen, and the administering of the mucosal binding component to the mucosal surface is performed before, during or after exposure of the same mucosal surface to the allergen.
14. The method according to claim 12, wherein immunological tolerance is induced against a mucosal antigen associated with an autoimmune disease of the gastrointestinal tract, and the mucosal binding component is administered to the gastrointestinal tract.
15. A method for treating an autoimmune condition in an individual, comprising inducing sustained immunological tolerance according to the method of claim 1.  
*sub C<sup>3</sup>*
16. The method of claim 15 wherein the autoimmune condition is rheumatoid arthritis and the inducing antigen is a type II collagen peptide.

17. The method of claim 15, wherein the autoimmune condition is multiple sclerosis and the inducing antigen is a myelin basic protein peptide.

18. The method of claim 15, wherein the autoimmune condition is Type I diabetes and the inducing antigen is an insulin peptide.

19. A method of decreasing the risk of rejection in a recipient of a tissue graft transplanted from a donor, comprising inducing immunological tolerance in the recipient to cells of the donor according to the method of claim 1 by administering to a mucosal surface of the recipient a composition comprising an effective combination of an inducing antigen and a mucosal binding component in an unconjugated form.

20. A method of decreasing the risk of graft-versus-host disease in a recipient from a tissue graft transplanted from a donor, comprising inducing immunological tolerance in the donor to cells of the recipient according to the method of claim 1 by administering to a mucosal surface of the donor a composition comprising an effective combination of an inducing antigen and a mucosal binding component in an unconjugated form.

21. A pharmaceutical composition for inducing sustained immunological tolerance according to the method of claim 1, comprising an effective combination of the inducing antigen and the mucosal binding component in an unconjugated form.

22. A pharmaceutical composition for mucosal administration in the treatment of Type I diabetes or insulitis, comprising an effective combination of insulin peptide and a mucosal binding component in an unconjugated form.

23. The pharmaceutical composition of claim 22, wherein the mucosal binding component is a cholera toxin B peptide.

24. The pharmaceutical composition of claim 22, further comprising a metal cation.
25. The pharmaceutical composition of claim 22, wherein the metal cation is  $Zn^{++}$ .
26. A method of preparing the pharmaceutical composition of claim 22, comprising combining the insulin peptide with the mucosal binding component at the weight ratio of the effective combination.

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